DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NEC Display Solutions Ltd
% Mr. Tony Hsu
Prodigy Technology Consultant Co., Ltd.
1F, No. 181, Sec 2, Wunhua 1st Road,
Linkuo, New Taipei City, 24447
TAIWAN

February 6, 2015

Re: K150145
Trade/Device Name: 31.5 inch Color LCD Monitor MD322C8
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: January 15, 2015
Received: January 22, 2015

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150145

Device Name
Medical Display, MD322C8

Indications for Use *(Describe)*
The MD322C8 color display is intended to be used for displaying and
viewing of digital images for diagnosis by trained physicians.
To guarantee the display performance as specified, it must only be used for in
Conjunction with NEC approved display controllers.
MD322C8 cannot be used for a life-support system.
This device must not be used in digital mammography.
This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary of Safety and Effectiveness

As required by 807.92

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Mr. Satoru Kotani

Manager

NEC Display Solutions Ltd.

4-28, Mita 1-chome, Minato-ku, Tokyo, Japan

Ph: +81-465-85-2384

Fax: +81-465-85-2393

2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

15th January 2015

4. DEVICE NAME

Trade Name:	MD322C8 31.5” Diagnostic Imaging LCD monitor
Model Name:	MD322C8
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)
Product Code:	PGY

4. PREDICATE DEVICE

MD210C3 3MP Color LCD Monitor by NEC Display Solutions Ltd. (K142951)

5. DEVICE DESCRIPTION

Medical Display, MD322C8 is a 31.5” Color LCD monitor that displays image for medical use. It provides 3840*2160p resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDED USE

The MD322C8 color display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used in conjunction with NEC approved display controllers.

MD322C8 cannot be used for a life-support system.

This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

7. SE Comparison Table:

Comparison tables between MD210C3 & MD322C8

Items	**MD210C3**	**MD322C8**
510(k) Number	K142951	
Panel Size and Type	21.3" TFT Color LCD Monitor	31.5" TFT Color LCD Monitor
Pixel Pitch	0.212 mm x 0.212mm	0.182 mm x 0.182mm
Display Color	1,073,741,824	1,073,741,824
Viewing Angles (^{o})	H:176, V:176	H:178, V:178
Scanning Frequency (H, V)	31.5-94.8, 126.3kHz , 30, 50-85 Hz	31.5-133.2kHz , 24-87 Hz
Native Resolutions	2048X1536 (Landscape) 1536X2048 (Portrait)	3840X2160 (Landscape) 2160X3840 (Portrait)
Brightness	400 cd/m2 calibrated, 800 cd/m^2 Max.	200 cd/m2 calibrated, 350 cd/m^2 Max.
Contrast Ratio	1400 : 1 (typical)	1000 : 1 (typical)
DOT Clock	214.3 MHz	214.3 MHz
Input Signals	Two connectors: one DVI-D, one display port (Display port comply with standard V1.1a, applicable to HDCP	Two connectors: one DVI-D, one display port (Display port comply with standard V1.1a, applicable to HDCP
Input Terminals	DVI-D, Display port	DVI-D, Display port
USB (option) / Standard	No	No

Active Display Size (H x V)	Landscape: 433mmX325mm Portrait: 325X433mm	Landscape: 697.9mmX392.6mm Portrait: 392.6X697.9mm
Viewable Image Size	540 mm (diagonal)	801 mm (diagonal)
Luminance Calibration	Software	Software
Default Gamma	1.8,2.0,2.2 DICOM part 14	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Input Rating	1.1-0.44A	1.51-0.6A
Power Save Mode	<2W	<5W
Dimensions (W x H x D)	W: Landscape: 473mm Portrait:373.4 mm H: Landscape:393.6-543.6mm Portrait:490.6-593.4mm D: 235.5 mm	W: Landscape: 744.8mm Portrait:440.8 mm H: Landscape:463.4-613.4mm Portrait:707.1-737.0mm D: 301.6 mm
NET Weight	11.8 kg	17 kg
Intended of use	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment
Certifications & Standards	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM

Display Testing:

- Display Reflection
- Luminance Response
- Luminance Uniformity

- Display Resolution
- Display Noise
- Veiling Glare
- Display Chromaticity
- Miscellaneous Tests

Summary: Test results showed minor differences between MD322C8 and MD210C3, however these differences are minor and were within the acceptable range of DICOM part 14.

CONCLUSION

1. These two devices have the same target population of trained practitioner in hospital; it shares the same design, same performance and is the same in radiation safety (EN60601-1-2), mechanical safety, electrical safety (AAMI/ES 60601-1) human factors and DICOM conformance. It use similar material, and have same compatibility with environment and other device. The SE Comparison Table compares the principal characteristics of two devices. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to MD210C3 by NEC Display Solutions Ltd. (K142951)